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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

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Application Number

09/816,152

Filed

03/26/2001

First Named Inventor

William A. KNAUS et al.

Art Unit

3626

Examiner

L. Najarian

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☒ attorney or agent of record. 36,902
Registration number _____☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

Signature

James Remenick

Typed or printed name

202-347-0066

Telephone number

February 24, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wm. A. KNAUS & Richard D. MARKS

Application Number: 09/816,152

Filed: March 26, 2001

Title: BROADBAND COMPUTER-BASED NETWORKED SYSTEMS FOR CONTROL AND
MANAGEMENT OF MEDICAL RECORDS

Group Art Unit: 3626

Examiner: Lena A. Najarian

MAIL STOP - AF

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Arlington, Virginia 22313-1450

Dear Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant respectfully requests the United States Patent and Trademark Office ("PTO") to review the rejections set forth in the final Office Action, mail dated September 23, 2005.

I. Brief Prosecution History

Applicant received a non-final Office Action, mail dated June 17, 2005, wherein applicant's claims stood rejected, under 35 U.S.C. § 102(e), as allegedly anticipated by Segal et al. (US 2001/0041991; "Segal"), and also under 35 U.S.C. § 103(a), as allegedly obvious over Segal in view of Malik (US 2001/0037219; "Malik") and Segal in view of other prior art references.

In this Office Action, the Examiner re-interpreted a great many of the elements of the claimed invention. Applicant filed a response traversing each rejection and also the Examiner's re-interpretations as improper and also internally inconsistent. Applicant also furnished an affidavit, under 37 C.F.R. § 1.131 with supporting evidence (the "Affidavit"). In accordance with M.P.E.P. § 715, the Affidavit demonstrates that, prior to the filing dates of both Segal and Malik, the inventors had conceived and/or reduced to practice the elements of the claimed invention actually found in Segal and Malik. In other words, if the Examiner agreed with Applicant that her re-interpretations were incorrect, the rejections would be withdrawn. However, if the Examiner refused, the Affidavit would render the rejections moot. The Examiner next issued a final Office Action mail dated September 23, 2005, reasserting the same rejections. No rejections were reconsidered and the Examiner refused to modify her reinterpretation of the claims. The Examiner now asserted that Applicant's Affidavit failed to demonstrate conception and/or reduction to practice "*of the whole invention claimed or something falling within the claims*" (final Office Action, page 15), because she was unable to locate applicant's *entire* invention in the Affidavit, and because Applicant failed to show a nexus between the Affidavit and the claimed invention. Because

the Examiner's analysis contains a series of material errors, including a disregard of the MPEP, reconsideration is appropriate.

II. The Claim Element of "Nonrepudiation"

Nonrepudiation is positively recited as an element of Applicant's claimed invention (e.g., claims 1, 8, 9, 25, 26 and 54). As recited in claim 1, medical information contained within medical records is verified as accurate and correct such that: *"one or more records of the collection possess a characteristic of nonrepudiation."* This element is also clear from the specification: *"Medical records that are verified as accurate attain the aspect of nonrepudiation (i.e. that the accuracy and correctness of the information [in the medical record] is as good or better than exists at the source from which the records were obtained) and may for all purposes be relied upon"* (specification, page 17, lines 14-17). Applicant respectfully asserts that this claim element is understood by those of ordinary skill in the art. Applicant is not incorporating a definition from the specification, but merely demonstrating that the specification is consistent with the context and the plain meaning of this term in the claims.

III. The Claim Element of "Certification"

Certification is positively recited as an element of Applicant's claimed invention. (e.g., claims 10, 11, 21, 22, 41-43 and 45). As recited in claim 10, the invention comprises a collection of medical records wherein *"each medical record is certified as accurate."* As stated by Applicant: *"The invention may include a form of medical record that can be completed at one of a plurality of certification levels"* (specification, page 15, lines 12-13). *"Certification levels refer to standards of verification such as, for example, 'initial' being self-certification wherein the member certifies that the record is correct, 'basic' whereby the system provider certifies that the record is complete for all information gathered"* (specification, page 15, lines 22-25; and claims 20, 37, 43). Applicant respectfully asserts that this claim element is understood by those of ordinary skill in the art. Applicant is not incorporating a definition from the specification, but merely demonstrating that the specification is consistent with the context and plain meaning of this term in the claims.

IV. Segal Does Not Disclose or Suggest the Claimed Invention

Segal does not disclose or suggest at least the elements of "certification of medical records" (claims 10, 11, 21, 22, 41-43 and 45) and "nonrepudiation of medical records" (claims 1, 8, 9, 25, 26 and 54) as these elements are claimed by Applicant. The Examiner's re-interpretation of these elements is based on a distortion of claim terms to shoe-horn these elements into portions of Segal. This is hindsight and improper.

The Examiner asserts that "nonrepudiation of medical records" and "certification of medical records" are disclosed in Segal (see non-final Office Action, pages 6-7, 9, 11, 13 and 14, and final Office Action, page 5, 10, and 18-19). The Examiner specifically points to paragraphs 8 and 131 in Segal, the relevant sections of which states that, *"Inherently, these computerized records are more organized, accurate, and accessible in comparison to paper-based records."* (Segal, Paragraph 0008), and "image

server 126 performs quality assurance checks on the images to verify diagnostic quality” (Segal, Paragraph 0131).

However, in the non-final Office Action, the Examiner asserts that nonrepudiation is disclosed in Segal at Paragraphs 8 and 131, and certification is disclosed at Paragraph 8 (see pages 6-7). In the final Office Action, the Examiner asserts the opposite, that nonrepudiation is disclosed in Paragraph 8 (and now adds Paragraph 137: “*data retrieval, like data acquisition, is convenient, accurate, easily available, and secure.*”) and that certification in Paragraph 131 (see pages 18-19). Being difficult to understand, these rejections have been nearly impossible to argue because the Examiner is not using words in their plain meaning or with an defined meaning. The claims, supported by the specification, demonstrate that the presence or absence of accuracy in a record is neither necessary nor sufficient for “certification” or “nonrepudiation,” each of which requires something additional beyond accuracy, as the claims make clear. This goes to the meaning of “accuracy.” For example, in one embodiment there is the additional step of verification (see claim 1). In another embodiment there is the additional step of vetting (see claim 20). Applicant’s position is simply that Segal’s statements are relevant to neither nonrepudiation or certification. Segal’s stated proposition is only that electronic medical records are inherently more accurate than paper-based records, and also, that it is important to perform quality assurance checks on images to verify diagnostic quality. These statements are clear and unambiguous to those skilled in the art, but not relevant to Applicant’s claimed invention.

Applicant respectfully asserts that the Examiner failed to perform a proper analysis and, besides ignoring plain meaning and context, the Examiner’s assumptions clearly involve hindsight, which is impermissible in analyzing questions of prior art. Applicant’s claim terms are clear to those skilled in the art, and the specification provides consistent guidance. Segal is also clear to those of ordinary skill in the art, and does not disclose or suggest either nonrepudiation or certification.

For at least these reasons, Applicant respectfully requests that all rejections based on Segal be withdrawn for failure to disclose Applicant’s claimed invention and for failure to establish a *prima facie* case of obviousness.

V. The Examiner’s Requirement that Applicant’s Affidavit Disclose the Entire Invention as Claimed in the Application is Contrary to the MPEP

The Examiner’s erroneously asserts that Applicant must state the entirety of its claimed invention in the Affidavit for the Affidavit to be considered sufficient and acceptable (final Office Action, page 15). This is incorrect. As stated in MPEP § 715.02, Applicant only needs to show that the Affidavit contains the elements of the claimed invention that are found in the supposed prior art:

[A]n affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the activity relied upon. If the affidavit contains facts showing a completion of the invention

commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient....(Emphasis added.)

The Examiner's analytical approach in reviewing Applicant's Affidavit is contrary to the MPEP, and thus, clear error. Both Segal and Malik should be removed as prior art references in view of Applicant's Affidavit. Further, because the Examiner provided no comments regarding Malik and Applicant's Affidavit, Malik at least should be removed as a prior art reference and all claims rejected over Malik be declared allowable.

VI. Even the Invention in the Examiner's Re-Interpretation is Disclosed in the Affidavit

In the Office Action the Examiner states that she was unable to locate "the invention of the claims" within the Affidavit (final Office Action, page 15). Erroneously, the Examiner focuses her review on disclosures in the Affidavit that are allegedly *absent* from Applicant's claims:

"... the product description of the PatientDirect system (which appears to be the closest item to the subject of the present invention) given at page 4 of the 'Executive Summary' document makes references to elements not present in any of the recited claims, namely, an 'Internet document transmission service', a 'second opinion/discount broker strategy', and an 'XML/HTTP protocol with encryption' (final Office Action, page 15).

This is further error because the factual analysis is wrong. Contrary to the Examiner's reading, as is clear to one of ordinary skill in the art, the entirety of the Affidavit evidence is directed to Applicant's invention and discloses the entire basic inventive concept; and the Examiner cited portions of the Affidavit that are highly relevant to Applicant's claims:

- "XML/HTTP protocol" with encryption is typical of secure communications over the Internet. This is the essence of a "broad-band, computer-based networked system" as set forth in the preamble to claim 1;
- Applicant's claimed invention directly involves "document transmission" over the Internet (see claim 4); and
- The "second opinion/discount broker strategy" is related to the element of non-repudiation as set forth in many of the claims including claim 1 (note for example the reference to "certification authority" at page 24 of the Affidavit).

These examples illustrate how the Examiner improperly analyzed Applicant's Affidavit and, as a consequence, mischaracterized many aspects of the Affidavit that are highly relevant to the instant claims. It appears to Applicant that the Examiner analyzed the instant claims using one interpretation of the claim elements and then analyzed the Affidavit using another. The Examiner cannot have it both ways under the MPEP – she cannot arbitrarily redefine "certification" and "nonrepudiation" one way in part of her analysis, and then revert to a different, mutually exclusive, set of definitions in another part. Either the rejections are erroneous or Applicant's Affidavit is sufficient to swear behind both Segal and Malik. Therefore, allowance is compelled.

VII. There is "No" Nexus Requirement in 37 C.F.R. § 1.131

For reasons that are at best unclear, the Examiner stated (multiple times including during the Interview of October 20, 2005) that Applicant's Affidavit fails because there is no "nexus" between the

Affidavit and the instant claims (final Office Action, page 15). This also is clear error. The requirement for a "nexus" between an Affidavit and a claimed invention is found only under 37 C.F.R. § 1.132, not 37 C.F.R. § 1.131.

VIII. The Examiner's Requirements for the Affidavit are Unsupported in the MPEP

In the Advisory Action, the Examiner asserts that Applicant's Affidavit lacks "precision, clarity and deliberateness" with regard to the words: (i) "broad-band" in the preamble of claim 1; (ii) "non-repudiation" also in claim 1; and (iii) "only" in claim 1, line 10. This standard of review is nowhere in the MPEP; so the Examiner's attempt to impose it cannot be supported. Affidavit evidence must be clear to those of ordinary skill in the art (see, e.g., MPEP 715.02), and Applicant's Affidavit fully and clearly meets that standard.

IX. The Examiner's Failure to Review Claims 20 and 37 is Error

Applicant respectfully notes that the Examiner never reviewed certain of the claims in either the non-final Office Action or the final Office Action. For example, there is no disclosure in any of the cited references relating to claims 20 or 37 with regard to the element: "accuracy and correctness of said at least one medical record is better than exists at the source site from which the medical record was obtained." None of the cited references, nor any comments by the Examiner, discloses or suggests a computer-networked system wherein the medical records are *more* accurate than the records collected from the source sites from which the records were originally obtained. At least these claims should be immediately declared allowable.

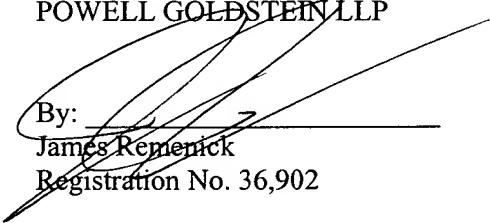
Conclusion

For at least these reasons, Applicant respectfully requests withdrawal of all rejections in the final Office Action, including all prior art rejections based on Segal and Malik, and the prompt issuance of a Notice of Allowance.

In the event that any additional fees are deemed necessary with the filing of this Request, the Commissioner is authorized to charge those fees to the undersigned's **Deposit Account No. 50-1682** referencing Attorney Docket No. 144009.00100.

Respectfully submitted,
POWELL GOLDSTEIN LLP

Date: February 24, 2006

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